

REMARKS

The application has been amended and is believed to be in condition for allowance.

Previously, claims 1-20 were pending. This amendment cancels claim 20 in order to introduce new independent claim 21. Independent claim 1 is also amended.

The Official Action indicates that a certified copy of the UK application 9919681.8 has not been filed with the Patent Office. However, note that the certified copy of the underlying British application was filed with the International Authority in connection with the PCT application and thus forms a part of the record. Normally, the U.S. Patent Office obtains the necessary underlying application from the International Authority.

The Official Action objected to claim 1. Responsively, claim 1 has been amended.

Applicants acknowledge that claims 3, 4, 6, 7, 10-17, 19 and 20 were objected to but were not either substantively or formally rejected. Accordingly, it appears that these claims are directed to allowable subject matter.

Claims 1, 2, 5, 8, 9 and 18 were rejected as obvious over SIMONS et al. 5,871,494 in view of PARSONS 5,569,189.

The invention concerns a lancet that is an improvement over the prior art "one size fits all" approach of presetting the force at which the hammer drives the prickling needle.

That is, in the prior art the spring urging the hammer forward has a set, invariant compression force and thus the speed at which the needle is moved is also set. But, skin thickness and toughness will vary from patient to patient. The invention allows a user to set the spring compression force appropriate to the user's skin conditions. Thus, the user is able to vary the force which acts on the hammer and needle in order to vary the speed with which the needle is ejected into, e.g., a finger, so that the patient can obtain a small blood sample. In this way, each user can adjust the need speed to suit their own circumstances to achieve the greatest comfort while ensuring an adequate blood sample will be achieved.

In the inventive device, a hammer 29 is released by a trigger 34 so that the hammer is driven forward to eject a lancet 24 by a compression driving spring 38. By axial adjustment of a barrier 39 (through rotational cam action) the user can adjust the compression of the spring and thereby the force at which the hammer will be driven by the spring upon the hammer's release. Varying the force acting on the hammer varies the speed of the lancet.

Consider SIMONS first. SIMONS discloses a spring 532 which determines the extent of the pressure that the user must apply to the skin in order to cause a trigger 538 to release a catch 540 so as to release drive spring 552.

The barrier 528 identified by the Official Action changes the compression of a spring 521 which does not meet the requirement of acting between the barrier and the hammer (drive spring 552 acting on the hammer).

In this regard, only the trigger load is adjusted. There is no adjustment to "a spring acting between the barrier and the hammer,...with the spring compressed to a degree determined by the axial adjustment of the barrier."

That the teaching of SIMONS is limited to adjusting the trigger load (by the user pushing the device against the skin to create welling up of the skin to an extent sufficient to release the trigger) is apparent from column 3, lines 27-50; column 4, lines 5-7; column 12, lines 55-64; column 14, lines 54-61; column 15, lines 41-47; and column 16, lines 24-28 and 43-45.

Comparing the claim 1 recitations to SIMONS, the barrier 528 identified by the Official Action changes the compression of a spring 521 which does not meet the requirement of acting between the barrier and the hammer (drive spring 552 acting on the hammer).

Thus, although SIMONS discloses a drive spring 552 positioned to the rear of the hammer 542, the features of the barrier being axial adjustable to vary the compression of the drive spring is missing.

Indeed, the Official Action acknowledges that SIMONS fails to position the adjustable barrier to the rear of the

hammer and that SIMONS teaches adjusting the compression of another spring for another purpose. Thus, SIMONS contains no teaching or suggestion as to varying the speed at which the needle is ejected by the lancet.

Whereas SIMONS is a needled blood sampling device, PARSONS is a needle-less drug delivery device. That is, these are two very different devices both as to structure and purpose.

As to PARSONS, there is disclosed a drug injecting device that involves injecting drugs under pressure without the use of a needle. Accordingly, there is no disclosure as to adjusting the injecting speed of a needle to make a blood sample draw.

PARSONS is non-analogous to SIMONS as there is no needle being moved in PARSONS, and the movement of the needle is essential to SIMONS. The uses and structures of these two devices are very dissimilar. There is no reason for one of skill as to SIMONS to look to a needle-less device such as PARSONS. Indeed, the PARSONS device is taught as an alternative to a needled drug delivery system device.

What PARSONS does disclose is a screw 42 which holds in place a spring 34, taking up any slack in the spring, when the device is being assembled. Note that the screw 42 is covered by a back end plate 222 as part of the assembly and is not accessible for user adjustment.

The teaching of PARSONS is to set a spring actuated piston to move an ampule assembly plunger to force liquid medication to be hypodermically injected at an injection site (Abstract). See also column 3, lines 60-67 teaching the spring storing a sufficient amount of energy to result in a hypodermically injected liquid at an injection site.

Achieving a hypodermically injected liquid is of course not a problem for a lancet, e.g., the SIMONS device.

Nor does PARSONS teach the spring storing an amount of energy that is set (adjustable) by a user. See column 7, lines 30-33 teaching the user being able to fill the ampule assembly. Note that the user's use and operation of the PARSONS device by the user is mentioned in several places within the patent specification. But nowhere is there any teaching that the user sets or adjusts spring 34. Thus, PARSONS only teaches a fixed, set compression on spring 34.

Therefore, even if the references are combined, the resulting SIMONS device would not include a user-adjustable barrier that sets the degree of compression on the spring propelling the hammer.

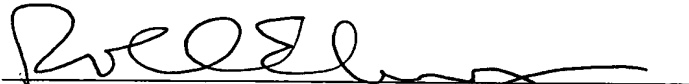
Reconsideration and allowance of claim 1 are respectfully requested. Allowance of claim 21 is also solicited.

In view of the above, applicants believe the present application is in condition for allowance and an early indication of the same is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



Roland E. Long, Jr., Reg. No. 41,949
745 South 23rd Street
Arlington, VA 22202
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

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